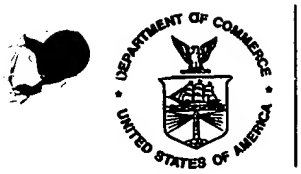

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/283,318	03/31/99	SMITH J	

HM12/0814

JACK V SMITH
PO BOX 5895
ASHEVILLE NC 28813

EXAMINER	
FOLEY,S	
ART UNIT	**PAPER NUMBER**
1648	4

DATE MAILED: 08/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/283,318	SMITH, JACK V.	
	Examiner	Art Unit	
	Shanon A. Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *5 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 7, 9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restiction

This application contains claims directed to the following patentably distinct species of the claimed invention: I: claims 5 and 8, drawn to a liquid assay, and II: claims 6, 7, 9, and 10, drawn to solid phase assay.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Jack V. Smith on July 31, 2000 a provisional election was made without traverse to prosecute the invention of species II, claims 6, 7, 9, and 10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5 and 8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: obtaining a test sample, contacting the test sample with an antigen or antibody in a buffer, and detecting the presence of HIV antibodies by a change in UV absorbance or color intensity in the visible spectrum. Claims 2, 3 and 4 lists reagents or components that "can be" selected for use in the method. Are these reagents or components actually selected? Also, there is a typo in claim 3, where the word "be" should follow "can".

Applicant has confirmed by telephone that the dependency of claims 9 and 10 should rest with claims 6 or 7. However, the claims as written refer to claim 1. It is applicant's responsibility to amend these claims in his response to this Office action to correct it. Claims 6, 7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 7 are dependent on claim 1, yet fail to point out which steps of the method disclosed use the ingredients from claim 1. The claim in step (a) refers to "successively"

impregnating an absorbent carrier matrix with reagent solutions. What is the order of solutions intended by "successively"?

Claims 9 and 10 refer to "specific gravity concentration". This term has not been defined by the claims and remains unclear as to what this refers to. The claims also refer to the use of creatinine, crystatin C, or specific gravity to normalize the sample. It is unclear how these can be used to accomplish the normalization. What is the sample "normalized" to? Is there a specific concentration necessary for the samples before employing the test method? Claim 9 refers to reagents that "can be" used to normalize the sample. Is it possible to use these reagents or not? Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: method steps to determine how the sample is normalized. As written, it is unclear what steps someone practicing this invention would utilize creatinine, crystatin C, or specific gravity to normalize a sample.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,447,837, H. Urnovitz.

The patent discloses a test strip used to detect the presence of an antigenic substance, see abstract. The invention also provides a test strip comprising an antigenic substance bound to the

first area, an anti-human antibody bound to the second area, and a positive and negative control bound to the third area, see column 2, lines 25-32. Antibodies were diluted in phosphate-buffered saline (PBS), see column 11, lines 36-37, anticipating claim 3. The method steps directed in claim 6, steps (a)-(d) are anticipated in figure 4 and described in full detail in column 5, line 63-column 6, line 16, and example 1, column 10, lines 53-column 12, line 63. In a preferred embodiment, the sample to be tested is urine, see column 3, line 19, and the antigenic substance being detected is a virus or a viral protein from HIV-1 or HIV-2, see column 4, lines 51-56, anticipating claim 2. A description of a examples directed to detecting HIV antibodies using urine as a test sample can be found in column 24, lines 16-59. Other examples of using the test strip with blood or serum can be seen in examples 1-3, columns 10, line 57-column 15, line 68, anticipating claim 4. The test strip is equipped with a detectable label, see column 10, lines 12-16 or color indicator to enable the practitioner to readily observe the test results, see column 12, lines 49-63 and column14, lines 37-39, anticipating claim 1. Claims 9 and 10 in the application are drawn to a method of normalizing the sample of urine before application to the test strip or lateral flow device. The patent describes pretreating the test sample to avoid non-specific binding of proteins to antibodies present on the test strip, see column 5, lines 33-62. Pretreating urine to normalize a sample is well known in the art. Therefore, in test H, column 24, lines 16-59, results of concentrated (treated) urine results are compared with unconcentrated urine results. The conclusions drawn from the example is that the untreated, unconcentrated urine had as conclusive results as the conclusions drawn in tests directed to the concentrated urine and blood.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is further rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,447,837, H. Urnovitz as applied to claims 6, 7, 9 and 10 above, and further in view of US 5,712,172, Huang, et al.

See the teachings of Urnovitz above. In addition, Urnovitz teaches detection of the antigen requires antigen detection located at specific regions on the test strip, see column 7, lines 29-42. Urnovitz does not teach the use of lateral flow to detect antigens as a diagnostic tool, but Huang, et al. does, see column 3, line 60-column 4, line 12. The only difference in the claims to that in the prior art is the antigen detected. The reference teaches the specific example of detecting the presence or absence of human chorionic gonadotropin (hCG) to determine pregnancy in women. The reference defines the "analyte" as a compound to be detected or measured in the test sample, see column 4, lines 47-48. The reference suggests that the compound of interest could be antigenic in nature, including proteins or peptides. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the use of a urine sample's natural ability to flow laterally from an application zone to the reaction zone by capillary action. Therefore, one would have been motivated to combine the teachings of Huang, et al. in using lateral flow of the sample to migrate toward the specific reaction sites on the test strip and further to a colored indicator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
August 9, 2000

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600